



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,934	12/11/2003	Howard Allen Ketelson	2437 US	7305

26356 7590 08/06/2004
ALCON RESEARCH, LTD.
R&D COUNSEL, Q-148
6201 SOUTH FREEWAY
FORT WORTH, TX 76134-2099

EXAMINER

PEZZUTO, HELEN LEE

ART UNIT	PAPER NUMBER
----------	--------------

1713

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/732,934	KETELSON, HOWARD ALLEN	
	Examiner	Art Unit	
	Helen L. Pezzuto	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1713

DETAILED ACTION

Applicant's amendment to the specification filed in the preliminary amendment on 3/10/04 is acknowledged. Currently, claims 1-4 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 3/10/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 101

2. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The "use of" recited in these claims constitute non-statutory subject matter.

Claims 1-2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

Art Unit: 1713

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b, e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffman et al. (US-588) or WO 02/30571 or Kidoaki et al. (Langmuir, 2001, 17, 2402-2407) or Bohanon et al. (J. Biomater. Sci Polymer Edn., 1996, 8(1), 19-39) or Dong et al. (ACS Symposium, 1987, 236-244).

Art Unit: 1713

US 5,998,588 to Hoffman et al. discloses the process of producing site specific interactive molecular conjugates by coupling polyNIPAAm to biomolecules such as proteins (col. 8, line 24 to col. 9, line 11; working examples; claims), with utilities in various chemical/biochemical application.

WO 02/30571 discloses a method of treating various surfaces using surface adsorbing polymers including N-isopropylacrylamide polymer and copolymers, which serves to decrease adsorption of organic materials (i.e. proteins, polypeptides) onto said surfaces. Suitable surfaces include polymethyl methacrylate, polydimethylsiloxanes, polyurethane which falls within the scope of the instant contact lenses and medical devices.

The Langmuir article is related the study of interactions between PNIPAAm graft layer and plasma proteins as a function of layer thickness.

Bohanon et al. (J. Biomater Sci polymer Edn) disclose the surface analysis of the adsorption of proteins and cells on oxidized silicon surfaces modified/grafted with NIPAM polymers, resulting in the prevention of protein adsorption on said modified surfaces.

Dong et al. (ACS Symposium) studied the immobilization of enzyme within copoly(N-isopropylacrylamide-acrylamide) gels, and the temperature dependence of the complex.

All prior art discussed above uses NIPAM polymers for competitive binding/adsorption of proteins to surfaces. The examiner is of the position that the recited property or function of NIPAM polymer for reduction of protein adsorption/deposits on the surfaces of medical devices/contact lens are considered inherent in the prior art, though not explicitly shown. The burden is placed upon the applicant to provide clear evidence that the respective composition do in fact differ. In any event, it would have been obvious to one skilled in the art to use NIPAM polymer taught in prior art to reduce protein adsorption, in light of their competitive binding/adsorption properties to protein molecules as taught in the references.

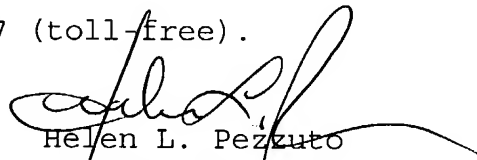
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen L. Pezzuto whose telephone number is (571) 272-1108. The examiner can normally be reached on 8 AM to 4 PM, Monday thru Friday.

Art Unit: 1713

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Helen L. Pezzuto
Primary Examiner
Art Unit 1713

hlp